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09/699,372	10/31/2000	Courtney Hudson	18966.0002	7828
23517	7590	10/21/2005	EXAMINER	
SWIDLER BERLIN LLP			PORTER, RACHEL L	
3000 K STREET, NW			ART UNIT	
BOX IP			PAPER NUMBER	
WASHINGTON, DC 20007			3626	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/699,372

Applicant(s)

HUDSON, COURTNEY

Examiner

Rachel L. Porter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005 and 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-24 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-24 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the communications filed 4/13/05, 7/11/05 and 7/19/05. Claims 1, 3-5, 7-24, and 39 are pending. Claim 39 is newly added.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/05 has been entered.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 4/13/05, has been considered.

### ***Claim Objections***

4. Claims 3-5 are objected to because of the following informalities: Claims 3 and 4 recite that they are dependent from claim 2. However, claim 2 has been canceled. For examination purposes, the Examiner is interpreting these claims as being directly dependent from claim 1, instead of canceled claim 2.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3-5, 7-14, 17-24 and 39 rejected under 35 U.S.C. 102(e) as being anticipated by Knight (USPAP 2002/0099570).

[claim 1] Knight discloses a method for matching patients with clinical trials, comprising:

- receiving patient profile information for a patient at a server connected to a computer network, the patient profile information submitted by a user at a terminal connected to the network; (par. 68)
- comparing the patient profile information with acceptance criteria for clinical trials stored in a database, the comparison performed by the server; and (par. 63,69))
- automatically, determining whether the patient prequalified for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria; and (par. 63)
- if the patient prequalified, for any of the clinical trials notifying the user that the patient has prequalified for at least one specific clinical trial; (par. 73—trial contact information appears)

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- presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials; (par. 70)
- determining whether the user prequalifies for at least one specific clinical trial based on the users response to the targeted questions; and (par. 70)
- storing the responses to the targeted questions. (par. 70-73)

[claim 3] Knight teaches a method further including providing the user with instructions for enrolling in the clinical trial for which the user has prequalified. (par. 70 and 73)

[claim 4] Knight teaches a method further including asking the user a plurality of questions and creating a patient profile based on the responses to the plurality of questions. (figure 1; par. 68—e.g. gathering demographic data)

[claim 5] Knight teaches a method of claim 4, wherein the step of asking the user a plurality of questions includes: asking the user one or more static questions; asking the user one or more dynamic questions which are selected based on the user's responses to other static and dynamic questions; and creating a the patient profile based on the responses to the static and dynamic questions. (Figures 1, par. 68, 72-75)

[claim 7] Knight teaches a method of wherein static questions, dynamic questions, and targeted questions are provided with a plurality of answer options, and the user may

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select one or more answer options in order to answer the questions. (Figure 3-6; par. 75-77)

[claim 8] Knight teaches a method of claim 7, wherein the user is required to submit an answer in a specified format, the specified format being suitable for evaluation by a computer program process. (par. 57: e.g. web-based interface)

[claim 9] Knight teaches a method further including updating the static questions, dynamic questions, or answer options. (par. 84-85)

[claim 10] Knight teaches a method wherein the network is the internet. (par. 57: e.g. web-based interface; par.75—web pages presented)

[claim 11] Knight teaches a method wherein the user is provided with an application to submit for a clinical trial for which the patient has prequalified. (par. 73—e.g. contact information ; Figures 9-10, par.80-81—enrollment information)

[claims 12-13] Knight teaches a method wherein the application (i.e. enrollment information) filled out by the user and submitted on-line to the server (Figures 9-10), and forwarded to the clinical trial site. (par. 80-81)

[claim 14] Knight teaches a method wherein the patient profile is forwarded to the clinical trial site with the application. (par. 125)

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[claim 17] Knight discloses a method wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical trial.

(par. 65-68)

[claim 18] Knight teaches a method wherein the acceptance/matching criteria include geographic location. (par. 76/Fig. 4—geographic location and preferences are match criteria)

[claim 19] Knight discloses a system for matching patients with clinical trials, comprising:

- a server connected to a network;(Figure 29)
- a data storage device included in the server, and (Figure 29)
- a database located in the data storage device, the database storing patient profile information for a patient and acceptance criteria for a plurality of clinical trials; (Figures 29-30, par. 68).
- the server comparing the patient profile information with the acceptance criteria for the clinical trials stored in the database, (par. 63,69)
- automatically, determining whether the patient prequalifies for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria; and (par. 63)
- if the patient prequalifies for any of the clinical trials, notifying the user that the patient has prequalified for at least one specific clinical trial; (par. 73—trial contact information appears)

- presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials; (par. 70)
- determining whether the user prequalifies for the at least one specific clinical trial based on the user's response to the targeted questions; and (par. 70)
- storing the responses to the targeted questions (par. 70-73)

[claim 20] Knight teaches a system wherein the database contains information on disease records; drug records; clinical trial records; and patient profile records. (par. 66; 75-77)

[claim 21] Knight teaches a system wherein a record in the database contains links to other related records. (Fig. 30)

[claim 22] Knight teaches a system wherein the server transmits a plurality of questions to the user over the network, the server also transmits a plurality of answer choices for each question, the server receives responses from the user, and the server builds a patient profile based on the responses. (Figures 1, par. 68, 72-75)

[claim 23] Knight teaches a system wherein the server retrieves a disease/subdisease record corresponding to a disease/sub-disease entered by the user, the disease/-sub-disease record containing links to question records, the server retrieving the question records to access questions to be provided to the user. (Figures 1-2; par. 72)



[Claim 24] The limitations of claim 24 recite a computer executable software instructions for causing a computer to perform the method recited in claim 1. Insofar as the method of claim 1 has been shown to be fully disclosed and computer implemented by the teachings of Knight in the rejection of claim 1, it is submitted that claim 24 is rejected for the same reasons provided in the rejection of claim 1, and incorporated herein.

[claim 39] Knight teaching method comprising the steps of:

- presenting at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of one or more clinical studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and contact Information; (par. 55, par. 128-131)
- automatically registering the individual with the database upon receipt of the registration and indicating information; (par. 131)
- automatically determining, in accordance with the indicating information and the registration information whether to provide notice of a clinical study related to said disease condition; (par. 133)
- providing notice of said clinical study; (par. 133)
- presenting a screening questionnaire associated with said clinical study; and (Figure 10)

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- storing in the database answers submitted in response to said questionnaire. (par. 80)

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight in view of Kraftson et al (USPN 6,151,581).

[claim 15] Knight discloses a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient record and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Michelson with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure

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that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 16] Knight teaches a method further including notifying the clinical trial sponsor when the user submits an application to the clinical trial site. (par. 131)

### ***Response to Amendment***

Applicant's submission of documents on 7/11/05 and 7/19/05, in an attempt to have an interference declared between the present application (09/699,372) and the Michelson et al application USPAP 2002/0002474A1 (09/923,385), cited as prior art, has been acknowledged. The documents have been reviewed by the Examiner, SPE Joseph Thomas, and TC Director John Love. However, because no patentable or allowable subject matter has been indicated in either application, it has been determined that no interference should be declared at this time between the two applications.

### ***Response to Arguments***

9. Applicant's arguments, see pages 10-11 of the response filed 7/11/05, with respect to the rejection(s) of claim(s) 1, 19, and 24 under 35 USC 102 (e) Michelson have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

The Examiner could not find support for the feature of automatically presenting a questionnaire or questions associated a specific clinical study to the person or caregiver in the Michelson Provisional Application, 60/178,634. Therefore this feature will not be given the benefit of the provisional application filing date.

However, upon further consideration, a new ground(s) of rejection is made in view of Knight (USPAP 2002/0099570).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

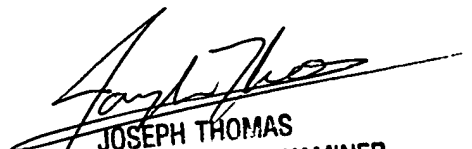
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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